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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/646,579 12/27/00 EBRINGER

A 092620269448

EXAMINER

HM12/1107

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FIELDS, I

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

11/07/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/646,579

Applicant(s)

EBRINGER, ALAN

Examiner

Iesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claims 10-14 are objected to because of the following informalities: The claims do not recite a Sequence Identification number. Each sequence recited in the claims must also contain a sequence number. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 1, 8, 10 and 13 are rejected under 35 U.S.C.112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is vague and indefinite in the recitation of "about two standard deviations above that of control samples". One of skill in the art would be unable to determine the metes and bounds of the limitations. For instance, what level of antibodies indicates a positive result? Without a clear definition as to what the value of the antibody level is one of skill in the art would be unable to determine "about two standard deviations" above a value that is not disclosed.

Claim 10 is vague and indefinite in the recitation of "conformationally similar". One of skill in the art would be unable to determine the metes and bounds of the limitations. For instance what constitutes a "conformational similar" epitope? Without a clear definition as to what constitutes as "conformational similar" one of skill in the art would be unable to replicate the claim.

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Claim 13 is vague and indefinite in the recitation of "conformationally similar sufficiently". One of skill in the art would be unable to determine the metes and bounds of the limitations. It is unclear what the applicant means by a "conformationally similar sufficiently" epitope. Clarification is requested.

The claim is further vague and indefinite in the recitation of "relevant antibodies". One of skill in the art would be unable to determine the metes and bounds of the limitations. For instance, what constitutes as a relevant antibody? Without a clear definition as to what the applicant is claiming one of skill in the art would be unable to replicate the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Prusiner et al. Hartnett et al. further in view of Marchalonis et al.

The claims are drawn to a method of detecting Spongiform Encephalopathy in mammals comprising testing a biological sample for antibodies.

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Prusiner et al. (US Patent 5,565,186) teach of a method of detecting Spongiform Encephalopathy in mammals comprising testing a biological sample for antibodies (See Entire Document; See Especially New Approaches to Investigating Prion Disease Section).

Harnet et al. (J Bacteriol 1990 172(2) pp. 956-66) teach the epitope sequence ISRFAWGEV.

Prusiner and Harnet et al. do not teach of a method of detecting Spongiform Encephalopathy in mammals comprising testing a biological sample for IgA antibodies.

Marchalonis et al. (Antibody as a Tool-The Applications of Immunochemistry, Chapters 2-3 and 13-14, John Wiley and Sons, UK 1982) teach the common methodologies used by those skilled in the art employing antibodies.

Given that 1) Prusiner et al. has taught of a method of detecting Spongiform Encephalopathy in mammals comprising testing a biological sample for antibodies and that 2) Harnet et al. has taught of the epitope sequence ISRFAWGEV and that 3) Marchalonis et al. has taught of the general state of the art employing antibodies it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to detect Spongiform Encephalopathy in mammals comprising testing a biological sample for antibodies such as IgA. One would have been motivated to detect disease in mammals employing such techniques because they are well known to the skilled artisan and commonly used in detecting prion diseases.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ilesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

November 2, 2001


MARK NAVARRO
PRIMARY EXAMINER